UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH DAKOTA

NORTHERN DIVISION

In Re: Baycol Products Liability Litigation	MDL No. 1431 (MJD) (JGL)
Alvin Mathern, Randall Merry, and Marlys Wagner, Plaintiffs, v. BAYER A.G.; BAYER CORPORATION; SMITHKLINE BEECHAM CORPORATION d.b.a. GLAXOSMITHKLINE; and GLAXOSMITHKLINE plc, Defendants.	**COMPLAINT** Demand for Jury Trial

02-1025

I. INTRODUCTION

Plaintiffs, by undersigned counsel, hereby institute this Complaint against Defendants Bayer Corporation, SmithKline Beecham Corporation d.b.a. GlaxoSmithKline, and GlaxoSmithKline plc (collectively "Defendants"), on behalf of themselves. This case involves the cholesterol-lowering drug cerivastatin designed, formulated, promoted, sold and distributed by Defendants in the United States as Baycol® ("Baycol") from February, 1998 until its withdrawal from the market on August 8, 2001. Baycol, as compared to other statin drugs in its class, caused a high incidence of rhabdomyolysis, a severe condition in which skeletal muscle suffers acute damage, causing in certain cases renal failure, liver damage, other organ damage or death.

II. PARTIES

1. Plaintiff Alvin Mathern is a resident of Mina, South Dakota, and took the drug Baycol at points in time between 1998 and August, 2001.

2. Plaintiff Randall Merry is a resident of Groton, South Dakota, and took the drug Baycol at points in time between 1998 and August, 2001.

3. Plaintiff Marlys Wagner is a resident of Freeman, South Dakota, and took the drug Baycol at points in time between 1998 and August, 2001.

4. Defendant Bayer A.G. is a German corporation engaged in the research, manufacture, marketing and sales of pharmaceuticals, including Baycol. Bayer A.G. manufactured, marketed and distributed Baycol worldwide (with the exception of the United States) under the trade name Lipobay. In the United States, Bayer manufactured, marketed, and distributed the drug as Baycol.

5. Defendant Bayer Corporation, a wholly owned subsidiary of Defendant Bayer A.G., is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

6. There exists, and at all times mentioned there existed, a unity of interest in ownership between Bayer A.G. and Bayer Corporation such that any individuality and separateness between them has ceased. These Defendants are the alter-egos of one another and exerted control over each other. At all times pertinent to this matter, they shared officers and directors and made all decisions in a uniform voice. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from one another will permit an abuse of the corporate privilege, would sanction fraud and promote injustice. Hereinafter, Bayer A.G. and Bayer Corporation will be referred to collectively as "Bayer."

7. Defendant SmithKline Beecham Corporation is a Pennsylvania corporation, with

its principal place of business located at One Franklin Plaza, Philadelphia, Pennsylvania. SmithKline Beecham Corporation is now a wholly owned subsidiary of Defendant GlaxoSmithKline plc and conducts pharmaceutical research and development in the United States under the fictitious corporate name GlaxoSmithKline.

8. Defendant GlaxoSmithKline plc is a British corporation headquartered at Glaxo Welcome House, Berkeley Avenue, Greenford, Middlesex, England. GlaxoSmithKline plc has its principal place of business in the United States at One Franklin Plaza, Philadelphia, Pennsylvania. In December 2000, GlaxoSmithKline plc acquired Glaxo Welcome and SmithKline Beecham. At all times relevant from December 2000, forward, GlaxoSmithKline plc was the holding company of SmithKline Beecham Corporation d.b.a. GlaxoSmithKline, which was engaged in the business of marketing, selling and distributing Baycol in the United States in partnership with Bayer.

9. Baycol was developed and manufactured by Bayer A.G., and sold, distributed, and marketed in the United States by Bayer Corporation together with SmithKline Beecham Corporation d.b.a. GlaxoSmithKline, and its predecessors.

10. On or about July, 1997, GlaxoSmithKline plc's predecessor, SmithKline Beecham Corporation, entered into an agreement with Bayer to promote, market and distribute Baycol. At all times relevant, GlaxoSmithKline plc and SmithKline Beecham Corporation conducted its marketing business from SmithKline Beecham Corporation's headquarters in Philadelphia, Pennsylvania.

11. Hereinafter GlaxoSmithKline plc, SmithKline Beecham Corporation d.b.a. GlaxoSmithKline, and SmithKline Beecham Corporation will be referred to collectively as "GlaxoSmithKline," unless otherwise specified.

12. There exists, and at all times mentioned there existed, a unity of interest in ownership between SmithKline Beecham Corporation d.b.a. GlaxoSmithKline and GlaxoSmithKline plc such that any individuality and separateness between them has ceased and these Defendants are the alter-egos of one another and exerted control over each other. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from one another will permit an abuse of the corporate privilege, would sanction fraud and promote injustice.

CIVIL CONSPIRACY/CONCERTED ACTIONS

13. At all times relevant to the matters alleged in this Complaint, each Defendant acted as the agent of the other Defendant, within the course and scope of the agency, regarding the acts and omissions alleged. Together, Defendants entered into an agreement to commit the acts alleged herein and engaged in a course of conduct in furtherance of those goals. Defendants acted in concert, aided and abetted each other and conspired to engage in the common course of misconduct alleged herein for the purpose of enriching themselves at the expense of Plaintiffs.

III. JURISDICTION

14. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332. There is complete diversity of citizenship between Plaintiffs and Defendants and the amount in controversy exceeds $75,000, exclusive of interest and costs.

15. Venue in this Court is proper in that Defendants do business here and Plaintiffs reside in this District.

IV. FACTUAL ALLEGATIONS

16. Cholesterol is a waxy substance produced in the liver, which plays a crucial role in maintaining cellular membranes and building certain hormones. Cholesterol and other fats cannot dissolve in the blood. Special carriers called lipoproteins must transport them to and from

the cells. There are several kinds of lipoproteins, but the ones of greatest concern are low density lipoproteins ("LDL") and high density lipoproteins ("HDL"). LDL is the major cholesterol carrier in the blood and is generically described as "bad cholesterol" (which is a component of low density lipoproteins or LDL) or HDL, which is generally described as "good cholesterol" (which is a component of high density lipoproteins or HDL). LDL is considered bad because it tends to leave deposits in the blood vessels as it travels through the blood stream. A high level of LDL cholesterol (160 mg/dl and above) reflects an increased risk of heart disease. Lower levels of LDL cholesterol reflect a lower risk of heart disease.

17. Baycol belongs to a class of drugs called statins, which block the activity of a specific enzyme involved in the production of cholesterol in the liver. Doctors commonly prescribe statins to patients to aid in lowering their cholesterol and triglyceride levels.

18. Baycol is more potent than other statins, because it takes effect at much lower doses. This, however, does not make Baycol more effective than other statins. The United States Food and Drug Administration (the "FDA") first approved statins in the late 1980's and early 1990's. Lovastatin (Mevacor®) was approved in 1987; Pravastatin (Pravachol®) and Simvastatin (Zocor®) were approved in 1991. All three drugs have similar chemical structures. The FDA approved other statins, including Fluvastatin (Lescol®), Baycol and Atorvastatin (Lipitor®) in 1997.

19. In June 1997, the FDA approved Bayer's application to market Baycol in 0.05mg, 0.1mg, 0.2mg, and 0.3 mg dosages in the United States.

AT THE TIME BAYCOL WAS APPROVED BY THE FDA, DEFENDANTS KNEW IT WAS LESS EFFECTIVE THAN OTHER STATINS ON THE MARKET

20. When the FDA approved Baycol, Defendants knew that it was less effective at the

approved dosages than other statin drugs already on the market. Indeed, the FDA specifically stated that Defendants could not make efficacy claims for Baycol as compared to the other marketed statins.

21. Since statins had been on the market for so long, and because Baycol made no claims to the FDA of being superior to the other statin drugs already on the market, Baycol was approved after clinical trials involving only about 3,000 test subjects. This number of subjects was far less than the numbers used in clinical studies involving other statins.

22. The cholesterol-lowering drug market is enormous. Defendants viewed Baycol as a blockbuster product with significant projected growth potential. Before its recall, Baycol was reported as having 5% of the market share of cholesterol-reducing drugs, and as being used by more than 700,000 patients in the United States.

23. Defendants marketed Baycol aggressively, claiming that it was an "exciting new alternative treatment option" because of the "ultra-low doses needed to achieve cholesterol reduction."

24. Defendants attained their market share by selling Baycol at a price significantly below that of other statins, which influenced insurance companies and HMO's to put Baycol on their lists of preferred drugs, and by aggressively selling the drugs through Defendants' sales force.

BAYCOL IS ASSOCIATED WITH SERIOUS ADVERSE SIDE EFFECTS

25. Doctors have associated Baycol with a serious medical condition known as rhabdomyolysis, in which skeletal muscle tissue suffers acute damage. Muscles feel sore and may cease to function. The cellular membranes of the muscle tissue, affected by rhabdomyolysis, are breached, releasing myoglobin and potassium into the blood stream from

inside the muscle cells. If the level of myoglobin in the blood reaches sufficient concentrations, kidney failure can result. Kidney failure leads to death about half of the time.

26. The body requires a certain ratio between the level of potassium inside and outside of cells to transmit electrical signals, such as the signals that stimulate muscle contraction. If enough potassium leaks from damaged muscle tissue, it can disrupt all electrical activity within the body, including that which controls contraction of the heart. Thus, rhabdomyolysis can also cause heart failure.

27. The first reported death due to rhabdomyolysis caused by Baycol ingestion was reported to the Bundesinstitut für Arzneimillel und Metizinprodukte, (the "BfArM"), the German equivalent of the FDA, in 1998.

28. Since that time, more than 100 additional deaths have been caused by or substantially contributed to Baycol use. More than 1,000 cases of muscle weakness or damage have been reported in association with the use of the drug. It is believed that far more instances of serious side effects that have been caused by, or associated with, the use of Baycol have occurred, but have not yet been diagnosed properly because Defendants failed to put the medical community on notice of the high incidence of rhabdomyolysis associated with Baycol use, especially at higher dosages. As a result, many patients' symptoms have gone undiagnosed, which ultimately caused an increased risk of harm to many patients.

29. The long-term consequences of rhabdomyolysis may include muscle tissue degeneration, damage to the kidneys, liver lesions, damage to other major organs and death. All of these effects can occur without any marked outward symptoms, or without any symptoms that would be recognized as associated with Baycol or with rhabdomyolysis by a doctor not specifically looking for that connection. Symptoms of rhabdomyolysis include, without

limitation, muscle pain, weakness, muscle tenderness, malaise, extreme fatigue, fever, dark urine, nausea and vomiting. The presence of creatinine kinase ("CK") levels two times or more above normal may be another indication of rhabdomyolysis.

DEFENDANTS KNOWINGLY CONCEALED THE DANGEROUS PROPENSITIES OF THEIR PRODUCTS AND ALL INFORMATION THAT WOULD SUGGEST THE ADVERSE EVENTS OCCURRED IN HIGHER THAN PREDICTED INCIDENCE

30. Defendants' marketing experience from 1998 through 1999 demonstrated a disturbing trend of Baycol users experiencing rhabdomyolysis, including reported deaths. Nevertheless, Defendants failed to disclose this data to the FDA before January of 1999.

31. In addition Defendants knowingly, intentionally, recklessly concealed, or negligently failed to disclose material information from the FDA and other government regulators, foreign governmental regulators, the medical community and from consumers and potential consumers, including Plaintiffs. Such concealment included, without limitation, the following:

(a) Defendants knowingly, intentionally, recklessly concealed, or negligently failed to disclose their own data from investigation and clinical trials and other analyses, studies, tests, understandings, and conclusions about the unreasonably dangerous nature of Baycol, especially at the higher dosages and in combination with gemfibrozil, adverse events associated therewith, and the significant defects represented thereby;

(b) Defendants knowingly, intentionally, recklessly concealed, or negligently failed to disclose that use of Baycol posed a significant increased risk of myalgia, myopathy, mysositis, and rhabdomyolysis, as well as damage to the kidneys, pancreas, and other organs, in its users, especially at the higher dosages, in combination with gemfibrozil, among other drugs, and taken alone, in post-menopausal women;

(c) Defendants knowingly, intentionally, recklessly concealed, or negligently failed to disclose that from its launch in 1998, the use of Baycol was associated with a significantly higher incidence of adverse events than had been reported in connection with any other drug in its class. All of these adverse events resulted in personal injuries, and many resulted in serious personal injuries and, in some cases, fatalities. Defendants deliberately failed to report much of this information to the medical community, the public or to the FDA, or any of the foreign government regulators;

(d) Defendants knowingly, intentionally, recklessly concealed, or negligently failed to disclose that from early after its launch, Defendants were aware that the medical community were persisting in co-prescription of Baycol, together with gemfibrozil, and were unaware of the drugs' high propensity to cause rhabdomyolysis in patients with concomitant use, however, Defendants knowingly, intentionally, reckless, or negligently failed to alert the medical community, place a proper warning on its packaging, or otherwise call attention to this dangerous propensity—which caused serious personal injuries and deaths in many patients;

(e) Defendants knowingly, intentionally, recklessly concealed, or negligently failed to disclose that Defendants' May 21, 2001 "Dear Healthcare Professional Letter" deceptively designated their conduct as responsible, and that "patient safety" was their "primary concern," when indeed, the letter euphemistically refers to the adverse consequences of co-prescription of Baycol together with gemfibrozil, and the adverse impact of prescription at the higher dosage—which previously had been aggressively promoted by Defendants. The letter failed to mention any of the reported deaths associated with either the co-prescription or the higher dosage. Defendants knowingly, intentionally, recklessly, or negligently to the significantly higher incidence of rhabdomyolysis associated with Baycol.

32. Consumers, including Plaintiffs, the medical community, and the health care insurers who required the consumers to use Baycol, were without access to the information concealed by Defendants as described herein, and therefore reasonably relied on Defendants' promotional materials, advertisements, "sales pitches" and free samples, promoting Baycol to the consumers. Had the consumers, the medical community, the health care insurance community, and the public known of the dangerous propensities of Baycol, and Defendants' own conclusions about those dangerous propensities, they would have taken steps to avoid that danger and would not have taken Baycol and/or would have never recommended that their patients and member insureds' use Baycol.

BAYCOL WARNINGS WERE INADEQUATE TO PUT THE MEDICAL COMMUNITY ON NOTICE OF THE TRULY DANGEROUS PROPENSITIES OF BAYCOL, TAKEN ALONE AT THE HIGHER DOSAGES, OR IN COMBINATION WITH GEMFIBROZIL AND ITS LACK OF EFFICACY AT THE LOWER DOSAGES

33. In 1998, when Baycol was first marketed, Defendants stated in the Warnings Section of the Physicians' Desk Reference (the "PDR") under "Skeletal Muscle" that: "[r]are cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with other [drugs in this class]. Myopathy, defined as muscle aching or muscle weakness, associated with increases in plasma creatinine kinase (CK) values to greater than 10 times the upper limit of normal, was rare (<0.2%) in U.S. cerivastatin trials."

34. In the 1998 "Adverse Reaction" section of the PDR, Defendants wrote: "In the U.S. placebo-controlled clinical studies, discontinuation due to adverse events occurred in 3% of cerivastatin sodium treated patients and in 3% of patients treated with placebo. Adverse reactions have usually been mild and transient. Cerivastatin sodium has been evaluated for adverse events in more than 3,000 patients and is generally well-tolerated."

35. In January 1999, the FDA required certain changes in Baycol labeling. In the Warnings section under "Skeletal Muscle," Bayer revised the text to read, "Rare cases of rhabdomyolysis (some with acute renal failure secondary to myoglobinuria) have been reported with cerivastatin and other drugs in this class." In addition, in the Adverse Reactions section, Bayer added the following language:

> The following events have been reported since market introduction. While these events were temporally associated with the use of Baycol, a causal relationship to the use of Baycol cannot be readily determined due to the spontaneous nature of reporting of medical events, and the lack of controls: hepatitis [liver inflammation], Myositis [muscle inflammation], rhabdomyolysis [the destruction of muscle cells], some with associated renal failure (most cases involved concomitant gemfibrozil), urticaria [hives], angioedema [excessive fluid retention in the vascular system], visual disturbance, blurred vision.
>
> (Bracketed materials added).

36. Given the high rate of adverse event reports associated with the use of Baycol, Defendants knew or should have known that a significant percentage of the adverse effects patients had experienced were causally related to Baycol use because these same adverse experiences had occurred in earlier controlled studies. Studies of people given Baycol demonstrated that a substantial number of Baycol users had significantly increased levels of the enzymes that induce destruction of muscle cells. In addition, the studies show that higher dosages of Baycol led to even higher enzyme levels in a greater number of Baycol users.

37. Despite these clinical trials and the experience of patients, Defendants persisted in seeking approval of higher dosages at 0.4 mg. To do so, Bayer undertook additional studies to demonstrate the safety and efficacy of Baycol. However, the studies demonstrated that adverse events were more frequent and severe as the dosage amount increased.

38. A study comparing dosages of 0.2 mg Baycol to 0.4 mg Baycol demonstrated that higher doses of Baycol were likely to cause significant cell death. In the study, eight patients receiving a 0.4 mg dose and five patients receiving a 0.2 mg dose of Baycol withdrew from the study due to adverse events. The incidence of adverse events that were linked as having a probable or possible relationship to Baycol was 21.4% in the 0.4 mg dose group and 19.8% in the 0.2 mg dose group. Elevated CK levels were reported in six patients in the 0.2 mg group and in twelve patients in the 0.4 mg group. Similarly abnormal liver function tests were reported in seven patients in the 0.2 mg group, and twelve patients in the 0.4 mg group. Although no patients in the 0.2 mg group experienced CK levels greater than three times the upper limits of normal, nine patients in the 0.4 mg group experienced CK elevations at this level.

39. Since Baycol was not as effective at the lower dosages as the other statins, in order to increase their market share, Defendants pushed for approval to market Baycol at 0.4 mg doses, which was approved by the FDA in May 1999, four months after the 1999 required Warnings change. Despite the data linking these clinical trials with the adverse experience of the Baycol users, especially at the higher dosages, after approval to market Baycol at 0.4 mg dosage, Defendants launched an advertising campaign trumpeting Baycol's "proven performance," "exceptional value" and "powerful new strength."

40. Notably, the advertisements barely discussed the risks associated with Baycol use, particularly the increased risks seen in the studies when Baycol dosage amounts were increased. Defendants continued to characterize rhabdomyolysis (the "important risk information" according to the FDA) as "rare." Rather than disclose the true rate of adverse events, in 1999, Defendants failed to identify rhabdomyolysis, increased CK levels or liver enzyme levels as an

adverse experience in the U.S. Placebo-Controlled clinical studies for marketed dosages of Baycol.

41. On October 25, 1999, the FDA's Division of Drug Marketing, Advertising and Communications sent Bayer a letter concerning Bayer's improper practice of disseminating misleading promotional materials about Baycol. In that letter, the FDA cautioned Bayer that the FDA had "become aware of promotional material for Baycol (cerivastatin sodium) that is false, lacking in fair balance, and otherwise misleading." The FDA noted that Defendants' promotional material also was "misleading . . . because it implies, without substantial evidence, that Baycol is superior to other competing products called HMG COA Reductase Inhibitors because of its synthetic properties." According to the FDA, Defendants' promotional materials also were misleading because they "implie[d] a clinical advantage for Baycol versus 'other statins' that is unsubstantiated" and any disclaimers given by Defendants in the promotional materials were in "small type [that did] not adequately correct the misleading implication."

42. The FDA's October 25, 1999 letter also notified Defendants that their uniform public promotional materials for Baycol were misleading for the following additional reasons:

- Defendants' "presentation . . . is misleading because it implies that Baycol is superior to other HMG's based on non-clinical (in vitro) data about the enzymatic properties of the HMG's."
- Defendants' graphical presentation "does not adequately correct the misleading implication."
- The presentation of "HDL-C efficacy information . . . is misleading because it overstates the efficacy of Baycol."
- Defendants' claim that Baycol was "significantly better than [the competing drug] Pravachol . . . is misleading because it implies that Baycol is superior to Pravachol without substantial evidence."
- "The studies utilized by Bayer to substantiate the superiority of Baycol versus Pravachol are inadequate."

- "The presentation of risk information . . . lacks fair balance. Promotional materials may be lacking in fair balance, or otherwise misleading if they fail to present information relating to side effects and contraindications, with a prominence and readability reasonably comparable to the presentation of efficacy information." In other words, Defendants were touting Baycol's efficacy but hiding or downplaying its side effects.

- Defendants improperly touted Baycol's efficacy but provided "very little risk information. In fact, Bayer presents the most important risk information (risk of myopathy, rhabdomyolysis, etc. . . .) with much less emphasis . . ."

43. The FDA's October 25, 1999 letter further directed Bayer to "immediately cease" its deceptive promotional materials.

44. Despite this stern warning from the FDA, Defendants did not stop misrepresenting the safety and efficacy of Baycol and continued to aggressively promote Baycol.

45. These and similarly deceptive advertisements by Defendants, individually and collectively, fraudulently misrepresented and were purposely intended to induce physicians, the medical community, the health care insurance community, and potential consumers that the product was safe and effective. They uniformly omitted and concealed adverse material facts known to Defendants that rendered such advertisements false and deceptive, and breached Defendants' duty of full disclosure.

46. These advertisements by Defendants were intended to cause and did cause American consumers to purchase Baycol. In the absence of the material information uniformly concealed by defendants, it may reasonably be inferred that Plaintiffs relied on the advertising campaigns of Defendants, and they may be presumed to have done so.

Despite Serious Adverse Events, Defendants Pursued Approval to Market, at Yet, A Higher Dosage

47. Despite the serious adverse events that had occurred in the post-marketing patient population, including fatality reports, and the signal that the drug could cause significant cell

necrosis, particularly at higher doses, Bayer once again sought approval to market a higher strength 0.8 mg tablet, permission to increase the daily dose to 0.8 mg and approval of Baycol as a treatment for additional disorders.

48. In order to receive approval, Bayer was required to undertake three "formulary switch conversion studies." These studies again demonstrated the dangers of Baycol and that the increased dose resulted in greater numbers of adverse events. Patients receiving the 0.4 mg dose and 0.8 mg dose continued to suffer serious adverse effects from Baycol.

49. In the large pivotal study for the increased dose, six patients at the 0.4 mg level withdrew from the study because of adverse events. Thirty patients in the 0.8 mg group withdrew from the study because of adverse events. The six patients in the 0.4 mg group who withdrew from the study cited elevated CK levels, elevated liver function tests, leg cramps and myalgia. The thirty patients from the 0.8 mg group who withdrew from the study cited elevated CK levels (ten events), elevated liver enzymes (seven events), leg cramps, myalgia and myasthenia. The researchers characterized several of the adverse events experienced in each group as "serious."

50. In this study, significant elevations in liver enzyme levels were seen in several patients. In the 0.4 mg group, three patients experienced liver enzymes tests of greater than three times the upper limit of normal, indicating serious liver injury. In the 0.8 mg group, this number jumped to eighteen patients with elevated liver enzymes greater than three times the upper limit of normal. Significant CK elevations were found in study patients. Six patients in the 0.4 mg group had elevated CK levels; twenty patients in the 0.8 mg group had elevated CK levels. Notably, most of these patients were asymptomatic and their muscle injury was only diagnosed through laboratory monitoring of patients in the study.

51. These increases in serum CK and liver enzymes levels should have signaled that Baycol was causing significant cell death in the patients. Over ten patients in this study experienced increased CK elevations greater than ten times the upper limits of normal. By comparison, in this same study, the placebo group reported no elevations of either CK or liver enzymes.

52. Despite this information, Bayer moved ahead with its plans. The FDA approved Bayer's request to market the 0.8 mg dose in July of 2000.

53. During all of this time, Defendants continued to receive notice of adverse events associated with Baycol, both directly from doctors and from the FDA, especially at dosages of 0.4 mg and higher.

54. Defendants extolled the introduction of the 0.8 mg daily dose of Baycol without disclosing the true risks the drug posed at this higher dosage. On the back cover of the January, February, March, May, June and July, 2001 issues of the American Heart Association's journal *Arteriosclerosis, Thrombosis, and Vascular Biology*, and in numerous other journals, Defendants promoted Baycol to physicians using large, colorful print advertisements depicting a swimmer pulling a tugboat with the caption "Whoever Thought Baycol Was That Powerful?"

55. Defendants promoted Baycol by advertising to doctors that Baycol was "more powerful" and so effective "84% of patients" reached their cholesterol level goals, while Defendants buried the risks of Baycol in fine print.

56. Furthermore, even the disclosures of potential risks were misleading. Instead of discussing the adverse reactions to Baycol at a 0.8 mg dose, Defendants lumped all the clinical studies together, including those from the initial new drug application for doses at 0.2 mg and below, and asserted "in clinical trials with 5,000 patients, the most common adverse events,

regardless of causality, were pharyngitis, rhinitis, headache and sinusitis." Defendants purposely failed to inform the prescribing doctors about the serious adverse reactions Defendants had causally connected to use of the drug, or the several deaths that Defendants were aware of that had been linked to Baycol.

57. By the fall of 2000, so many adverse events had been reported to the Arznei Telegram, a drug safety information bulletin based in Germany, that the German Health Ministry put the drug on a watch list. Bayer A.G. is a subscriber to the Arznei Telegram.

58. Adverse events continued to increase in number and be reported. By March 2001, the Arznei Telegram published a warning concerning the use of the drug. This warning was sent to Bayer A.G. and to the BfArM.

59. Since both Bayer Corporation and Bayer A.G. share officers and directors, and since Bayer Corporation was co-marketing the drug with GlaxoSmithKline, Defendants were aware of the growing number of adverse events reported concerning the use of Baycol.

IN APRIL, 2001, THE FDA AGAIN REQUIRES STRONGER WARNINGS

60. In April 2001, the FDA again mandated stronger label warnings for Baycol, emphasizing particularly the risks of co-prescription of gemfibrozil, with Baycol.

61. Before its recall in August of 2001, Baycol was often jointly prescribed and administered with gemfibrozil to improve the balance of triglycerides and good cholesterol.

62. On May 21, 2001, Bayer sent a the "Dear Healthcare Professional" letter that belatedly called attention to some of the dangers associated with Baycol use, particularly when combined with gemfibrozil. Nonetheless, Bayer continued to misrepresent and conceal the dangers associated with Baycol. And, still, Bayer insisted that, "When used as directed, Baycol effectively and safely treats patients with [high cholesterol levels]."

63. On July 16, 2001, France's drug control agency, L'Agence Francaise De Securite Sanitaire Des Produits Sante ("AFSSAPS"), issued a warning of problems related to Baycol use after learning that there were three reported deaths in Spain.

64. Defendants' Baycol warnings were insufficient because they were inadequate to prevent co-prescription of Baycol with gemfibrozil, and because Baycol, taken alone, was associated with a significant number of adverse events long before Defendants released this "Dear Doctor" letter.

65. Despite Defendants' knowledge of the inadequacy of the warnings, and of the dose-dependent and inherent dangers of Baycol use (especially when taken at higher dosages or in combination with gemfibrozil), Defendants continued to conceal Baycol's adverse effects and to market the drug throughout the United States and abroad to be administered at dosages of 0.3 mg and higher.

66. At all times during the pertinent time period, Defendants marketed Baycol to doctors as safe and highly effective. While the advertisements touting Baycol made statements regarding efficacy that were large and prominent, the disclosures of risks were embedded in lengthy fine print statements, and, therefore, were misleading in their presentation.

67. In July 2001, the European Medicines Evaluation Agency announced that it was investigating the side effects of Baycol.

68. On August 8, 2001, Bayer announced that it was withdrawing Baycol from the market for public safety reasons. At the same time, Defendants finally disclosed the true extent of the dangers associated with Baycol (which they knew or should have known long before August 2001) by issuing a letter to doctors stating that "[r]habdomyolysis is a serious, potentially

fatal, adverse effect of all statin drugs, including Baycol. It can occur with statin monotherapy, though the risk appears to be increased significantly by concomitant use of gemfibrozil (Lopid)."

69. The German Health Ministry has accused Bayer A.G. of grave errors in its information policy regarding the side-effects of Baycol. Defendants are charged with having withheld information on the adverse effects from the German Institute for Drugs and Medical Products for almost two months and then only making the information available on demand.

Plaintiffs were Damaged By Defendants' Wrongful Conduct

70. Defendants falsely and deceptively misrepresented or omitted a number of material facts concerning Baycol, including, but not limited to, adverse health effects caused by Baycol including the frequency, severity and rapid development of these adverse events.

71. Furthermore, through, among other things, their advertising campaigns, misleading communications with and concealment of information from the FDA, the medical community and the public, and despite their knowledge that Baycol was dangerous, Defendants continued to promote vigorously and advertise and promote Baycol.

72. Had Plaintiffs known of the full extent of the risks and dangers associated with Baycol, including that it was not as effective or safe as other drugs in its class, they would never have purchased or taken Baycol. Plaintiffs were proximately injured and suffered losses as a result of Defendants' knowing, intentional, reckless and negligent failures to disclose and other misconduct.

73. Defendants knew or should have known that Baycol created significant risks of serious injuries, including damage to the kidneys, liver and heart and other major organs. Defendants failed to make proper, reasonable, timely or adequate warnings about the risks associated with the use of Baycol.

74. By way of their wrongful misconduct, Defendants intended to and did supply Baycol to Plaintiffs that was unreasonably dangerous and in certain instances, deadly.

75. As a result of Defendants' fraudulent concealment, the applicable statutes of limitations have been tolled as to all of the claims of Plaintiffs.

Plaintiffs Are Entitled to Punitive Damages

76. As a result of Defendants' oppression, fraudulent concealment, wantonness, malice, reckless disregard for the safety of Plaintiffs, Plaintiffs are entitled to punitives or exemplary damages to the fullest extent necessary and punitive as plead in detail below.

COUNT I

STRICT PRODUCTS LIABILITY (FAILURE TO WARN)

77. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

78. Defendants, as the manufacturers and suppliers of Baycol, failed to provide proper warnings to physicians regarding all possible adverse side effects regarding the use of Baycol, as well as the severity and duration of such adverse effects.

79. Defendants failed to perform adequate testing that would have shown that Baycol possessed serious potential side effects with respect to which full warnings were needed.

80. Defendants, a manufacturers and suppliers of Baycol, failed to conduct adequate post-marketing warning and instruction because, after Defendants knew or should have known of the risk of injury and death from Baycol, Defendants failed to provide adequate warnings to physicians, and continued to aggressively promote Baycol.

81. As the direct and legal result of the defective condition of Baycol:

a. Plaintiffs suffered personal injuries;

b. Plaintiffs suffered economic loss, including loss of earnings and loss of earning capacity.

COUNT II

STRICT PRODUCTS LIABILITY (DESIGN DEFECT)

82. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

83. Baycol is defectively designed because the foreseeable risks exceeded the benefits associated with the design or formulation.

84. Additionally, Baycol is defective due to inadequate clinical trials, testing, study, and inadequate reporting regarding the results of same.

85. As the direct and legal result of the defective condition of Baycol:

a. Plaintiffs suffered personal injuries;

b. Plaintiffs suffered economic loss, including loss of earnings and loss of earning capacity;

c. Plaintiffs expended, and may in the future be required to expend, fair and reasonable expense or necessary health care, attention and services and incurred incidental and related expenses.

COUNT III

NEGLIGENT FAILURE TO WARN

86. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege:

87. Baycol was not accompanied by appropriate warnings of the increased risk of adverse side effects caused by the ingestion of Baycol.

88. Defendants negligently failed to warn consumers who took Baycol that it was dangerous.

89. Defendants' negligence was the proximate cause of the harm suffered by Plaintiffs.

90. As a direct and proximate cause of Defendants' negligence:

a. Plaintiffs suffered personal injuries;

b. Plaintiffs suffered economic loss, including loss of earnings and loss of earning capacity;

c. Plaintiffs expended, and will in the future be required to expend, fair and reasonable expenses for necessary health care, attention and services and incurred incidental and related expenses.

COUNT IV

NEGLIGENCE PER SE

91. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

92. Defendants were negligent per se because they violated applicable statutes and regulations relating to prescription drugs. Plaintiffs are persons whom these statutes and regulations were meant to protect.

93. Defendants' negligence was the proximate cause of the harm suffered by Plaintiffs.

94. As a direct and proximate cause of Defendants' negligence:

a. Plaintiffs suffered personal injuries;

b. Plaintiffs suffered economic loss, including loss of earnings and loss of earning capacity;

c. Plaintiffs expended, and will in the future be required to expend, fair and reasonable expenses for necessary health care, attention and services and incurred incidental and related expenses

COUNT V

BREACH OF IMPLIED WARRANTY

95. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

96. Defendants breached the implied warranty of merchantability because Baycol cannot pass without objection in the trade, is unsafe, not merchantable, and unfit for its ordinary use when sold, and is not adequately packaged and labeled.

COUNT VI

UNJUST ENRICHMENT

97. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if set forth herein and further allege:

98. Plaintiffs paid for Baycol for the purpose of reducing their cholesterol.

99. Defendants have accepted payment from Plaintiffs for the purchase of Baycol.

100. Plaintiffs did not receive a safe and effective cholesterol-reducing drug for which each Plaintiff paid.

101. It would be inequitable for the Defendants to retain this money because Plaintiffs did not in fact receive a safe and efficacious cholesterol reducing drug.

COUNT VII

MEDICAL MONITORING

102. Plaintiffs incorporate by reference all preceding allegations as if fully set forth herein.

103. As a direct and proximate result of Defendants' actions and omissions as described above, Plaintiffs have been exposed to a hazardous substance and as a result, suffer a significantly increased risk of contracting a serious injury or latent disease. This increased risk makes periodic diagnostic medical examinations reasonably necessary. Monitoring and testing procedures exist that make the early detection and treatment of such injuries or disease possible and beneficial.

104. In addition, certain of the Plaintiffs who have suffered physical injuries and harm as a result of their use of Baycol have also suffered an increased risk of future harm, and of contracting a serious latent disease as a result of their exposure to this hazardous substance.

105. The increased susceptibility to injuries and irreparable threat to the health of Plaintiffs resulting from their exposure to this hazardous substance can only be mitigated or addressed by the creation of a medical monitoring fund to provide for a medical monitoring program, including:

a. Notifying Baycol users of the potential harm from Baycol;

b. Funding further studies of the long term effects of Baycol on users;

c. Funding research into possible cures for the detrimental effects of using Baycol;

d. Gathering and forwarding to treating physicians information related to the diagnosis and treatment of injuries which may result from using Baycol; and,

e. Aiding in the early diagnosis and treatment of resulting injuries through ongoing testing and monitoring of Baycol users.

106. Baycol users have no adequate remedy at law in that monetary damages alone do not compensate for the continuing nature of the harm to them, and a monitoring program which notifies them of possible injury and aids in their treatment can prevent the greater harms which may occur immediately and which may be preventable if proper research is conducted and the health risks are diagnosed and treated before they occur or become worse.

107. Without a court-approved medical monitoring program, Baycol users might not receive prompt medical care that could detect and prolong their productive lives, increase prospects for improvement and minimize disability.

COUNT VIII

PUNITIVE DAMAGES

108. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if set forth herein and further allege:

109. Defendants acted wantonly, recklessly, intentionally, and maliciously, and with conscious disregard and indifference to the rights, safety and welfare of Plaintiffs and are, therefore, liable to Plaintiffs for punitive and exemplary damages in accordance with applicable state law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that this Court enter a judgment against Defendants and in favor of Plaintiffs and award the following relief:

1. Declare that Baycol is dangerous and defective;

2. Compensatory damages awarded on behalf of Plaintiffs against Defendants in an amount deemed appropriate by their trier of fact to compensate Plaintiffs for their pain and suffering as well as for their actual damages, including but not limited to,

medical, incidental, hospital, and service expenses, and loss of earnings and earning capacity;

3. Equitable/injunctive relief in the form of a medical monitoring program and a rehabilitation program, to be established and supervised by the Court and funded by Defendants, for the benefit of Plaintiffs and the prevention and amelioration of injury and future harm;

4. Punitive damages as allowed by law;

5. Prejudgment and post judgment interest on all damages as is allowed by the law;

6. Past and future mental and emotional distress damages;

7. Damages or a fund, as the Court may determine, for those plaintiffs who have suffered personal injury and require rehabilitation as a result;

8. Restitution of all purchase costs that Plaintiffs paid for Baycol, disgorgement of Defendants' profits, and such other relief as provided by law;

9. Costs, including expert fees and attorneys' fees and expenses, and costs incurred in the prosecution of this action; and,

10. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial on all claims so triable in this action.

Dated May 24, 2002.

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